K032915
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OCT 3 0 2003

GE Medical Systems
3000 N. Grandview Blvd
Waukesha, WI 53188

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Submitter Larry A. Kroger, Ph.D.
Senior Regulatory Program Manager
Telephone: (262) 544-3894, FAX: (262) 548-4768
Date Prepared: August 8, 2002`

PRODUCT IDENTIFICATION

Name: Advantage 4D option

Classification Name: Accessory to Computed Tomography System

Classification Panel 892 - Radiology

Classification Number: 892.1750

Manufacturer : GE Medical Systems
3000 N. Grandview Blvd
Waukesha, WI 53188, USA

Distributor: General Electric Medical Systems, Milwaukee, WI

Marketed Devices:

Option is substantially equivalent to:

Model:	Smart Breath Respiratory Compensation
Manufacturer:	General Electric Medical Systems
510(k) #:	K022919

Option also incorporates features derived from:

Model:	Advantage Sim 6.0.
Manufacturer:	General Electric Medical Systems
510(k) #:	K021780

Device Description:
Advantage 4D enables a patient to be scanned on a CT with normal breathing. CT data are acquired and images are reconstructed without image artifacts due to organ and tissue motion. CT Images are synchronized with respiratory signal coming from external device and organ/tissue motion within the CT data reflecting both the organ motions and the chest motion.

ATTACHMENT A

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The user can then visually determine the optimum phase to perform volume imaging and post processing □quantification, contouring, segmentation. The respiratory phase identification is also provided.
In addition, Advantage 4D has the capability to display DICOM Radiation Therapy Structure Sets and can be used for target or treatment volume verification. This new capability comes from features derived from Advantage Sim 6.0 (K021780).

Indications for Use:
Advantage 4D is a non-invasive software / hardware option that can be used to provide and display CT images of all phases of a breathing cycle for the evaluation of respiration-induced motion. The software will allow the user to retrospectively define the best respiratory phase from an image quality standpoint, and group images by the phase selected. Advantage 4D can also be used for target or treatment volume (DICOM Radiation Therapy Structure Sets) verification

Comparison with Predicate:

This device will use a similar technology to that already used by GE Medical Systems in our cleared devices Smart Breath Respiratory Compensation (K022919) and Advantage Sim 6.0 (K021780). Fundamentally, this device will use the same phase selection process that is used in Smart Breath Respiratory Compensation to group images based on respiratory phase. In addition, Advantage 4D will have the ability to display reformat images through a Cine Phase Movie, and to overlay RTSS (Radiotherapy Structure Sets) contours over multiphase CT slices. These additional features are inherited from the viewer of Advantage Sim 6.0 (K021780). A more detailed comparison is included in Attachment C of this submission.

Device Name	FDA Clearance Number
Smart Breath Respiratory Compensation	K022919
Advantage Sim 6.0	K021780

Adverse Effects on Health :
The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:
Advantage 4D Option does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features and technology of the Advantage 4D Option to be equivalent to those of Smart Breath Respiratory Compensation □K022919 and Advantage Sim 6.0 □K021780.

ATTACHMENT A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

GE Medical Systems
% Mr. Juergen Welte
Responsible Third Party
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K032915
Trade/Device Name: Advantage 4D Option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: October 14, 2003
Received: October 15, 2003

Dear Mr. Welte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

GE Medical Systems
3000 N. Grandview Blvd
Waukesha, WI 53188

STATEMENT OF INTENDED USE

510(k) Number (if known): K032915

Device Name: Advantage 4D

Indications For Use:

Advantage 4D is a non-invasive software / hardware option that can be used to provide and display CT images of all phases of a breathing cycle for the evaluation of respiration-induced motion. The software will allow the user to retrospectively define the best respiratory phase from an image quality standpoint, and group images by the phase selected. Advantage 4D can also be used for target or treatment volume (DICOM Radiation Therapy Structure Sets) verification

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use _____
(Per 21 CFR 801.109)

David G. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032915